Remarks

This paper responds to the office action dated July 26, 2007. The rejections and objections set forth in the office action are specifically traversed. Reconsideration is respectfully requested in view of the above claim amendments and these remarks.

Claims 22, 25, 27, and 35 are amended herewith. Claims 1-21, 23-24, 28-34, 36, 44-45, 49, and 52 have been cancelled, without prejudice.

The "new matter" rejection of claims 22 and 27 has now been overcome by this amendment. Specifically, claim 22 has been amended to replace the phrase "consisting of" with "including." Regarding the new matter rejection of claim 27, this claim has now been amended to be consistent with the description of the invention set forth in the patent application at page 18, line 29 through page 19, line 1.

The 35 U.S.C. § 112 rejection of claims 22, 25 and 28 has also been overcome by this amendment. Specifically, claim 22 has been amended to include the parts of a computer based system, including a processor, a memory and a display for presenting the recited graphical user interface.

The 35 U.S.C. § 101 rejection of claim 22 has also been overcome by this amendment. Specifically, the claim now clearly recites a statutory machine, *i.e.*, a computer implemented medical record system comprising a display, a processor and a memory for storing computer readable instructions that cause the processor to render a graphical user interface on the display.

Finally, the 35 U.S.C. § 103 rejection over Lavin in view of Campbell is traversed because the combination of these two references fails to disclose or suggest: (1) automatically selecting a visit outline from a plurality of stored visit outlines in response to a selection of a patient's primary reason for visiting a medical service provider input to a reason for visit data entry field; (2) a visit outline which guides the examination by the medical service provider and listing the types of information that should be collected and recorded into the medical record system, the presented visit outline including an item column listing information that should be collected by the medial service provider in relation to the selected primary reason for the patient's visit and a value column that lists the type or format of the collected information; and (3) dynamically modifying the presentation of the information set forth in the item column of the visit outline in response to a user making a selection from a pre-defined set of choices presented in the value column of the visit outline.

1. Lavin and Campbell Fail to Disclose or Suggest Automatically Selecting a Visit Outline

Independent claim 22 recites the function of automatically selecting a visit outline from a plurality of visit outlines stored in the memory. This automatically-selected visit outline is related to the reason for the patient's visit that is input to the recited "reason for visit data entry field." An example of this "reason for visit" data entry field is shown below in Figure 7 as item 84. The "reasons for visit data entry field" (item 84) shown in Figure 7 is a drop down box that allows the medical service provider to select a primary reason for the patient's visit. In the example shown in Figure 7, "Chest Pain" is the primary reason selected.

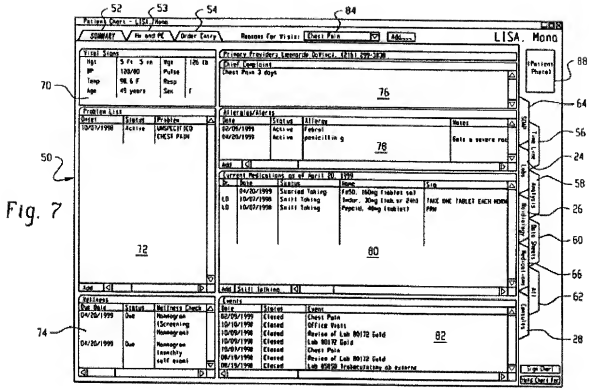


Fig. 7

The selections presented by this data entry field (item 84 in Figure 7) are linked, by the system, to one or more visit outlines that will assist the medical service provider by guiding the examination and by listing the types of information that should be collected and recorded into the medical record system. In the example of Figure 7, the selection "chest pain" is linked to a specific visit outline related to this problem and causes the system to automatically select and display the specific visit outline related to this problem. For example, as shown in Figure 8 of this application, set forth below, the selection of "chest pain" as the primary reason for the visit has triggered the "chest pain" visit outline in the patient history and physical examination screen. As shown in the left most column of the data entry screen, the

visit outline guides the examination by the medical service provider and lists the types of information that should be collected and recorded into the system.

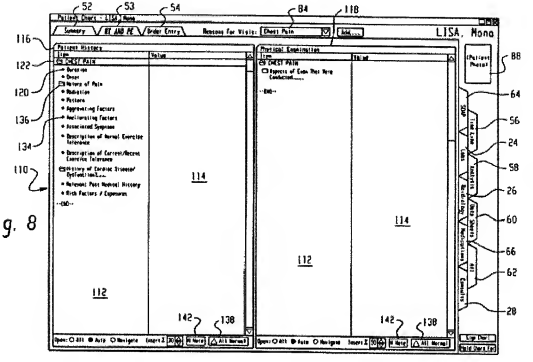


Fig. 8

If the medical service provider had selected a different reason for the patient's visit in the reason for visit data entry field (84), then the system would have automatically selected a different visit outline to guide the examination.

The office action admits that Lavin does not disclose the concept of a visit outline and thus it does not disclose the function of automatically selecting a visit outline from a plurality of stored visit outlines in response to the selection input to a reason for visit data entry field. (*See*, Office Action at page 6, "Lavin fails to expressly teach the selection received in the reason for visit data entry field automatically selects a visit outline. . .")

Campbell does not disclose this "automatic selection" function either. The office action refers to the following portions of Campbell in support of this teaching, but as clearly demonstrated below these portions of Campbell simply do not disclose the claimed functionality: (i) abstract of Campbell; (ii) col. 1, line 64 to col. 2, line 8; (iii) col. 2, lines 14-21; and (iv) col. 13, lines 10-18.

[57] **ABSTRACT**

A software system for managing a health care practice includes interactive software tools for conducting a physical exam, suggesting tentative diagnosis, and managing a treatment protocol. The physical exam software guides the user through a physical exam, prompting the user for input and dynamically generating context sensitive questions based on prior input. The diagnosis software generates a list of possible diagnoses based on the observations recorded from the physical exam. The user can interactively select a diagnosis by selecting a diagnosis from a rule out list and watching the display as the system dynamic updates the status of unresolved symptoms. The user can also select a treatment protocol, which is integrated with future physical exams. The treatment protocol is integrated such that future exam sessions reflect the status of the treatment protocol and remind the user which services need to be performed and when they should be performed.

The Abstract of Campbell refers to "physical exam software," and a "list of possible diagnosis," and "selecting a treatment protocol," but it does not disclose or suggest a system having a plurality of visit outlines as recited in claim 22, the visit outlines being automatically selected based upon user input to a reason for visit data entry field. In fact, this portion of Campbell tends to indicate that there is only one programmed type of physical exam as distinguished from the "plurality of" visit outlines that are programmed into the claimed system and which are automatically selected based upon the primary reason for the patient's visit. This is a very important advantage of the present invention because it enables the

medical service provider to more quickly gather the information necessary to make a diagnosis in response to the reason for the patient's visit, whereas in Campbell the user is likely required to enter data that is largely irrelevant to the patient's condition. Although Campbell's approach may be appropriate for a general physical examination in which there is no particular reason for the patient's visit, it is inefficient and time-consuming when the patient has come to the medical service provider with a specific problem, such as chest pain.

The following additional portions of Campbell relied upon in the office action further demonstrate a lack of any teaching or suggestion of automatically selecting a visit outline from a plurality of visit outlines stored in the system in response to the specific problem identified by the user:

> When installed in a medical office or hospital, the system software of the invention can be executed in a network configuration or in a stand-alone computer. The system software displays interactive user interface screens for conducting an interactive medical exam, generating diagnoses of abnormal observations, and managing a treatment proto-
>
> **2**
>
> col. The treatment protocol can be integrated with the interactive medical exam component of the system. For example, the doctor can select a treatment protocol from a user interface displaying computer generated diagnoses. In response, the system schedules the treatment protocol such that future interactive exam sessions display reminders to perform services in the protocol, and prompt the user to make observations related to the selected diagnoses. Once
>
> *(Campbell, col. 1, line 64 to col. 2, line 8)*

> The interactive medical exam component of the system displays physical exam screens that guide the user through a complete medical exam. The screens display predetermined observations and enable the user to select among the observations to record abnormal findings. The system dynamically updates the patient's record and evaluates the input to generate additional context sensitive prompts to record additional observations.
>
> (Campbell, col. 2, lines 14-21)

> When the user clicks on any of these buttons, the system launches a new screen for the selected part of the physical exam. The interactive exam screens guide the user through the physical exam. As user enters information (by clicking on buttons or entering text), the server dynamically updates the database and evaluates the data to determine whether to prompt the user for additional information by displaying questions and supplemental screens that prompt the user to input medical observations.
>
> (Campbell, col. 13, lines 10-18)

As clearly described in these portions of Campbell, his invention includes a single "physical exam" comprising a number of physical exam screens. These screens display predetermined observations and enable the user to select among the observations. Moreover, these "screens" are selected by the user of the system "when the user clicks on any of these buttons." Figure 4 of Campbell shows this manual or user selection of the various portions of the physical exam. When a user "selects" a button (420 in Figure 4), the system then brings up a predetermined physical exam screen (Figure 5) in response to the user selected portion of the physical exam.

Thus, Campbell teaches a single, predetermined physical examination which is broken down into a number of areas, such as "Overall Condition," "Coat and Skin," "Ocular," etc. The user of Campbell's system has to manually select one or more of these areas in order to be presented with a completely separate examination "screen" (Figure 5) that is used to collect information regarding the selected portion of the examination: "*The physical exam buttons represent the top level in a hierarchy of physical exam screens. The physical exam is broken into the following areas: 1) Overall Condition. . . 12) Behavioral. When the user clicks on any of these buttons, the system launches a new screen. . .* " (Campbell at col. 12, line 59 to col. 13, line 11)

Missing from Campbell is any disclosure or suggestion of linking the reason for the patient's visit, as input to the system in a reason for visit data entry field, with a specific visit outline that has been customized to guide the examination by the medical service provider in relation to the reason for visit. In Campbell, the examination screens are generic and unrelated to the reason for the patient's visit, whereas in the system disclosed and claimed in claim 22, the visit outlines are specific to the reason for the patient's visit and are designed to efficiently gather only the pertinent information relevant to that reason.

In summary, Campbell does not disclose or suggest a plurality of visit outlines, but rather teaches a single physical examination broken down into a number of areas. Moreover, Campbell does not disclose or suggest automatically selecting one of the plurality of visit outlines in response to a selection of the primary reason for the patient's visit, but rather teaches that the user must manually select a sub-set of the single physical examination

process. Therefore, because this claimed subject matter is not disclosed or suggested in either of Campbell or Lavin, the obviousness rejection should be withdrawn.

2. Lavin and Campbell Fail to Disclose or Suggest Visit Outlines Having an Item Column Listing and a Value Column Listing

Claim 22 also requires that the visit outlines include "an item column listing information that should be collected by the medical service provider in relation to the selected primary reason for the patient's visit and a value column that lists the type or format of the collected information." An example of this claimed "visit outline" is shown in Figure 8 of the present application, set forth below.

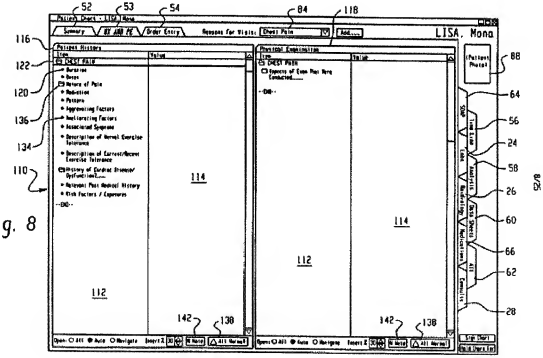


Fig. 8

As shown in this figure, the "visit outline" of the present invention includes a hierarchical item column listing (112) that is set forth in an "outline" form and which is configured to guide the examination by the medical service provider by listing, again in outline form, the types of information that should be collected. The claimed "visit outline" also includes a corresponding "value column" (114) which lists the type or format of the collected information.

Neither Lavin or Campbell is configured to present the medical service provider with such a claimed "visit outline" having an item column listing and a value column listing to guide the collection of pertinent information by the medical service provider. First, as noted above, neither reference discloses the concept of a visit outline at all, but rather each reference teaches a generic user-selected examination process. Second, neither reference uses the dual-column outline structure shown in Figure 8, and recited in claim 22, to guide the examination. Instead, Campbell uses a distinct and separate examination screen for each portion of his single physical examination process. These separate examination screens in Campbell are not organized into an "outline" form either as shown in Figure 8 and recited in claim 22, but rather include a plurality of buttons, check-boxes, and other selector means (See Figure 5 of Campbell) that result in a very cluttered interface screen. There is simply no notion in Campbell of attempting to guide the medical examination through an outline form as recited in claim 22.

Therefore, for this additional reason the 35 U.S.C. § 103 rejection over Lavin and Campbell should be withdrawn.

3. Lavin and Campbell Fail to Disclose or Suggest Dynamically Modifying a Visit Outline

Finally, claim 22 also recites the function of "dynamically modifying the presentation of the information set forth in the item column of the visit outline in response to a user making a selection from a pre-defined set of choices presented in the value column of the visit outline." In the present invention, as now claimed, the visit outline itself is dynamic and the information to be gathered that is displayed in the item column (112 in Figure 8, above) changes depending upon user selections presented in the value column (114 in Figure 8, above). This functionality is completely missing from either Lavin or Campbell.

As noted above, neither Lavin or Campbell disclose the concept of a visit outline as now recited in claim 22, and therefore neither reference can possibly disclose a dynamic visit outline in which the presentation of the information set forth in the item column of the visit outline changes in response to user selections in the value column. Although Campbell refers to a dynamic system, it does not disclose a visit outline, nor does it disclose modifying an item column portion of a visit outline in response to user selections. At best, Campbell discloses a process for collecting additional data, but this is in the context of additional data entry screens, not in the context of modifying an existing data entry mechanism such as a visit outline.

Therefore, for this additional reason the 35 U.S.C. § 103 rejection over Lavin and Campbell should be withdrawn.

For all of the reasons noted above, the obviousness rejection of claims 22 and 35 over Lavin in view of Campbell should be withdrawn.

Although applicants maintain that the current amendment to the claims and the foregoing remarks put all of the claims in condition for allowance, applicants also specifically traverse the rejection of claims 25 for the reasons noted below.

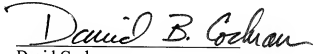
Claim 25 depends from claim 22 and adds the limitation of a carepath module that is linked to the selected visit outline for suggesting a particular medical treatment in response to the data input in the first, second and third screens into the patient's chart, wherein the carepath module also automatically determines that additional data entry is required to evaluate the patient's condition in order to make a suggestion and prompts the user of the medical record system to input the additional data.

The portions of Campbell relied upon in the office action as disclosing a carepath module refer to a "treatment protocol" which is displayed to the medical service provider. This appears to be a simple look up table type of implementation that does not provide any logic or intelligence built into the carepath. In the carepath module described in claim 25, for example, the suggestion of a particular medical treatment is made in response to the data input to the first, second and third data entry screens, and, moreover, the carepath module is smart enough to determine that additional data is required in order to make a suggested treatment and thereafter automatically prompts the user to enter the needed data. In Campbell, by distinction, the "treatment protocol" must be manually selected by the medical service provider, it is not "linked to" a selected visit outline, nor does it make suggestions based upon

the data input to the system, nor does it automatically prompt the user to enter needed data suggest a treatment: "*The doctor can then launch a protocol by clicking on the protocol button. In response, the client sends a message to the server, which changes the status of the diagnosis to Undergoing therapy. . . To generate a protocol the server looks up the protocol in a protocol table using the selected diagnosis as a key.*" (Campbell, col. 17, lines 32-40) As demonstrated by this portion of Campbell, the "protocol" is manually selected by the doctor, and it is not linked to any visit outline but instead appears to be linked to a tentative diagnosis. Thus, Campbell does not disclose or suggest the functionality set forth in claim 25 and therefore the obviousness rejection of this claim should be withdrawn.

This application is now in condition for allowance.

Respectfully submitted,



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